Coverage Issues in the Government Reimbursement of Drugs: Some Legal and Policy Issues

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Charles A. Lubinsky

Although the 103rd Congress, despite much anticipation, did not enact any health care reform legislation, many of the problems which led to proposals and consideration of reform still remain. Health care costs are still increasing,[1] though growth has slowed.[2] Large portions of the United States population remain uninsured or underinsured.[3] It would not be surprising if some form of health care reform reappeared on the scene some time in the near future.

In this paper, I discuss one element of government health care coverage which must be considered as part of any comprehensive health care reform effort ó drug coverage.[4] Drugs are an important part of health coverage, and are likely to become even more significant[5] Payments for drugs were approximately 8.1 percent of total health care expenditures in 1991, totaling over $60

[1]Carolyn S. Donham, HEALTh CAREFIN. REv., Summer 1994, at 165,190.

[2]Id.

[3]Approxiinately 14 percalt were not covered by health insurance in 1991. 1995 WORLD ALMANAC & BOOK OF FAcrs 967(1994).

[4]I concentrate on coverage issues rather than picing issues because the former have more relation to Food and Drug Law and because I can only cover ˜ much. This is not to say that pricing issues, such as required rebates under Medicaid, are inelevant to a comprehensive examination of governn˜it reimbursement of drugs. However, that paper will have to wait for another time.

[5]Sean D. Sullivan et al., The Economics of Outpatient Drug Coverage for the Elderly: Implications for Healthcare ˜ GENERATIONS, June 22, 1994, at 55 (noting tint most chronic diseases attacking older people are controllable through drugs).

billion.[6] In addition, drugs are intricately involved with many of the problems which people see as requiring reform. Drug prices, like the cost of health care in general, have increased at a much faster rate than other prices in the economy since 1980.[7]

Insurance coverage of drugs, both public and private, varies considerably.[8] Although the elderly population is one of the major consumers of drugs,[9] Medicare, the primary elder insurance plan, does not generally provide coverage for prescription drugs.[10] Drug reimbursement under government insurance has been debated since the initial passage of the Medicare and Medicaid legislation.[11] Congress reexamined the issue throughout the 1970s and 1980s.[12] Drug coverage under Medicare was actually provided in the Medicare Catastrophic Coverage Act of 1988,[13] but then rescinded when most of the act was repealed a year later.[14] Drug coverage was proposed as a benefit for both the Comprehensive Benefit Package under the Alliances and under Medicare as part of President Clinton's proposed Health Security Act of 1994.[15] States have the option under Medicaid to cover drugs, and most do.[16]

[6] 5.W. Letich, National Health Care Spending in 1991, HEALTH AFF., Spring 1993, at 94,96-98. Of this $60 billion, **$36** billion was for prescription drugs while $24 billion was for non-prescription drugs and other medical nondurables. Ii

[7] Sullivan, ˜g note *5,* at *55.* However, nonprescription drugs appear to have a much slower inflation rate. 5˜ Letsch, supa note 6, at 98.

[8] Sullivan. ˜ note *5.*

[9] Sullivan. note 5.

[10] 21-42 and accompanying text.

[11] Stephen H. Long, Prescription Dnigs ami the Elderly: Issues and Options, HEALTh AFF., Spring (11)1994, at 157, 158.

[12] Id.

[13] Thjb. L No. 100-360,102 Stat. 702 (1988). See notes 70-74 and accompanying text

[14] Medicare Catastrophic Coverage Repeal Act of 1989, Pub. L. No. 101-234, 103 Stat. 1979(1989).

[15] H.R. 3600/S.1757, 103d Cong., 2d Seas. (1994). See notes 56-69 and accompanying text.

[16] See notes *43-55* and accompanying text.

The paper is divided into three sections. In the first section, I describe four different public sector schemes for government coverage of drugs. First I outline the existing drug coverage system under the two dominant government health care programs, Medicare and Medicaid. I then outline proposals contained in the Medicare Catastrophic Coverage Act of 1988 and the Health Security Act of 1994. The second section examines coverage differences between the four schemes and shows where each plan allocates flexibility regarding coverage issues. The final section addresses some of the difficult issues surrounding drug coverage, and discusses whether and how the four schemes described address these issues. I examine three problems: (1) Should drugs be covered at all under a government health insurance plan? (2) How should coverage be related to approval by the Food and Drug Administration? and (3) How should over the-counter drugs be treated? While this discussion may not definitively show how a future drug benefit should look, it does outline a number of issues which should be taken into account.

I.A Description of Four Drug Reimbursement Systems

Of the four drug reimbursement systems described below, all but the Clinton Plan deal exclusively with government reimbursement. (The Clinton Plan also includes a drug benefit in its Comprehensive Benefit Plan applicable to all health plans.) However, drug reimbursement is obviously an issue with relevance to private as well as public insurers.[17] There are a number of reasons for focusing on public insurance. Public insurers are quite large and are often

[17] willy˜ Linda C. Higgins, Off-lahel Rx: Insurers Starting to Balk MED. WORLD NEWS, Oct. 24,1988, at22.

industry leaders when change happens.[18] This is especially true for the elderly, who are large users of prescription drugs. Also, focusing on public insurance provides a simplified way to examine reimbursement issues. Finally, legislative reform is most likely to affect the public sector (barring passage of comprehensive health care legislation).

The first two descriptive summaries require a brief introduction. Medicare and Medicaid are both government-run health insurance systems, but are administered in very different ways. Medicare is targeted primarily at the elderly and disabled population and is funded and administered by the Federal government. Medicaid is targeted primarily at the poor and is jointly funded and administered by the Federal government and individual stales. As a result, while Medicare benefits are relatively uniform across states, Medicaid benefits vary widely both in scope and in degree.[19] However, the Federal government does set minimum standards for the Medicaid program. Both programs utilize local insurers (usually Blue CrosslBlue Shield or Aetna) to provide actual payments to providers.[20]

Medicare is divided into two separate programs, Part A and Part B.[21] Part A deals primarily with facility-based in-patient care, while

[18]Private insurers may even defer to Medicare determinations for coverage decisions. ˜, ˜ Bechtold v. Physicians Health Plan, 19 F.3d 322(7th Cir. 1994).

[19]g˜˜fly Terry S. Coleman, *U˜E&fr* ˜xmAm.Ba˜1g.Baim˜1ra˜menLkEI, 44FOODDRUG-COSM. U. 99(1990).

[20]There are a number of different terms used for insurers which distribute Medicare and Medicaid finids (carriers, intermediaries, and in some cases liMOs and other managed care organizations). Rather than parse these words into their specific technical meanings, I use carrier and fiscal intermediary interchangeably.

[21]The Medicare program as a whole is codified at 42 U.S.C.A. §* 1395-1395ccc (West Supp. 1994). Part A is described primarily at 42 U.S.C.A.I˜ 1395c-1395i-4 (West Supp. 1994), while Part B is at 42 U.S.CA. §§ 1395j-1 395w-4 (West Supp. 1994).

Part B deals with out-patient care and physician reimbursement. Part B requires a premium payment. Drugs are treated differently under the two different Parts, though the definition of a drug is defined statutorily for both sections. To fulfill the Medicare definition of a drug, the drug must be either included, or approved for inclusion, in one of the official drug compendia[22] or be approved by the facility medical staff's pharmacy or drug therapeutics committee.[23] FDA approval automatically fulfills the statutory requirement when used for the approved indication.[24] The statute provides an explicit exception for anti-cancer chemotherapeutic cancer drugs, which have been approved for a medically accepted indication and distributed by the National Cancer Institute.[25] Reimbursement under Medicare must also be reasonable and necessary.[26] Carriers under Medicare have significant discretion in deciding what type of drugs are reasonable and necessary in the absence of HCFA direction.

Under Part A, drugs are generally covered when provided as a benefit incident to a hospital visit. However, they must be furnished for use in the institution, must represent a cost to the institution, must be ordinarily furnished,[27] and must fit the Medicare definition of a drug. In general, this means that investigational or nonapproved drugs are not reimbursed.[28] However,

[22]Compendia include: (a) the U.S. Pharmacopoeia, (b) the Natiouial Formulary, (c) the U.S. Homeopathic Pharmacopoeia, **(d) AMA Drug** Evaluations, and (e) Accepted Dental Therapeutics. Medicare and Medicaid Guide(CCH) ∂ 1223 (Aug. 4,1994). This is essentially an updated version of the list given at 42 U.S.C.A. 5 1395x(tXl) (West Supp. 1994).

[23]42 U.S.C.A. § 1395x(tXl) (West Supp. 1994).

[24]Medicm and Medicaid Guide (CCII) ∂1223 (Aug. 4,1994). These are the Omup C drugs.

[25]42 U.S.CA § *1395x(tX2)* (West Supp. 1994). S˜ahaQ **Medicare and Medicaid Guide (CCH)** ∂ 27,201 (Aug. 28, 1994).

[26]42 U.S.C.A. § 1395y(aX 1) (West Supp. 1994).

[27]42 CFR 5409.13 (1993).

[28]Medicare and Medicaid Guide (CCH) ∂ 1223 (Aug. 4,1994).

unapproved uses of approved drugs may be allowed depending on the generally accepted medical practice in the community.[29]

Under Part B, prescription and non-prescription drugs purchased are not covered by Medicare, unless furnished by a physician[30] and fulfilling the Medicare drug definition. There are a number of statutory exceptions to this general rule. For example, Group C cancer drugs, as mentioned above, are reimbursable under both Part A and Part B.[31] Other exceptions include flu, pneumococcal and hepatitis B vaccines, some antigens, immunosuppressive drugs, and osteoporosis drugs (until December, 1995).[32] However, a notice of hearing by the Food and Drug Administration (FDA) under the Federal Food Drug and Cosmetic Act (FFD&CA) § *505*[33] regarding withdrawal approval for a drug (or a similar drug) not subject to the 1962 Drug Amendments[34] precludes reimbursement under Part B.[35] This restriction does not apply to Part A.[36]

In many ways the most controversial portion of the Medicare drug coverage requirements has been the general Medicare requirement that reimbursement be reasonable and necessary.[37] HCFA has interpreted this to mean

[29]y˜ ˜ Coleman, supra – ˜ at ˜

[30]Medicare and Medicaid Guide (CCII) ∂ 3126 (Nov. 3,1994).

[31]42 U.S.C.A. § 1395x(tX2) (West Supp. 1994). ˜al˜ **Medicare and Medicaid** Guide (CCII) ∂ 27,201 (Aug. 28, 1994).

[32]42 U.S.C.A. § 1395x(sX2) (West Supp. 1994).

[33]2l U.S.C.A. § *355.*

[34]Under § 703(cX3) of the Drug Amemiments of 1968, Pub. L 87-78 1 (1962).

[35]42 U.S.C.A. § 1395y(c) (West Supp. 1994).

[36]M˜li˜ and Mudicaid Guide (CCII) ∂ 1223 (Aug. 4,1994).

[37]A number of cases have been litigated contesting HCFA's determination of whether a drug was reasonable and necessary. ˜, ˜, Friedrich v. H.H.S., 894 F.2d 829(6th Cir. 1990) (rejecting plaintiffs claim that Medicare decision not to cover chelation was in contravention of the reasonable and necessary standard); Pulmocare Pharm. v. Sullivan. CV No. 91-1291-PA, 1992 U.S. Dist. LEXIS 14528 (D. Ore. l992Xupholding HCFA decision to not reimburse **drug** after FDA notified company of its lack of approval); National Council of Senior Citizens v. Hams, No. 80-157, MEDICARE ANDMEDICAID GUIDENEWDEV. ∂30,636,(D.D.C. Aug.27, 1980) (upholding HCFA decision to reimburse despite FDA action questioning effectiveness. This predated HCFA regulations that would now require action).

that the item in question must be (1) safe and effective, (2) not experimental or investigational, (3) cost-effective, and (4) appropriate.[38] If HCFA has not made a national coverage decision, the decision is left to the carriers)[39] Though experimental or investigational use drugs are not reimbursed by Medicare, the unapproved use of many FDA approved drugs is left to the Medicare carriers. Proposed Medicare rules state that breakthrough procedures are judged by a less stringent standard,[40] but it is unclear whether this applies to drugs as well as procedures.

Some cases have also addressed the question of whether HCFA regulations unlawfully interfere with the practice of medicine in violation of the Medicare statute.[41] However, these cases have not met with much success.[42]

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Because Medicaid[43] is primarily administered by the states, much variation exists regarding precise coverage of certain benefits. In fact, prescription drugs are an optional benefit under Medicaid. On the other hand, some

In all of these cases, the court upheld HCFA's determination of what is and is not reasonable and necessary. ˜g Hultmian v. Weinberger, 495 F.2d 1276(1974) (holding that the Secretary may not deny coverage retroactively when he believes the utilization review committee did not function properly).

[38]54 Fed Reg. 4302,4307 (1989) (to **be codified** at 42 C.F.R. § 405.380) **(proposed Jan. 30, 1989) (No final rule has** been promulgated). It was actually the settlement of a lawsuit which first provided HCFA with the impetus to propose regulations outlining the determination process for reasonable and necessary. Id.

[39]Id.

[40]Id.

[41]Nothing in this subchapter shall be constmed to **authorize any Federal officer or employee** to exercise and supervision or control over the practice of medicine or the manner in which medical services are provided.... 42 U.S.C.A. § 1395.

[42]˜, ˜g,, **American Medical Ass'n v. Mathews, 429 F.** Supp. 1179,1201.03 (N.D. Ill. 1977) (holding that MAC regulations for drug reimbursement don't interfere enough to came a violation). S mla˜ **Goodman** v. Sullivan, 891 F.2d 449(2nd Ct. 1989) (holding that Medicare was not required to pay for MRI procedure despite recommendation of physician).

[43]The Medicaid program is codified at 42 U.S.C.A. §j 1396-1396v (West Supp. 1994). ˜42 U.S.C.A. § 1396r-8(kX2) **(West Supp. 1994).**

states may choose to cover non-prescription drugs.

The Federal government provides guidelines for states which choose to provide drug benefits. One baseline is the statutory definition of covered outpatient drug.[44] The statute states that the drug must be available only by prescription[45] and must either be (1) FDA- approved,[46] (2) a pre-1962 drug (or a similar drug) which has not been determined to be a new drug or to have inadequate directions for use, or (3) a drug to which the 1962 Amendments do not apply[47] (and for which approval has not been withdrawn). The definition also includes prescription biological products (other than vaccines) and insulin drugs certified under § 506 of the Federal Food Drug & Cosmetic Act. The definition explicitly excludes drugs used for a medical indication which is not medically accepted[48] A medically accepted indication is either the FDA-approved use or a use supported by a compendia.[49]

States are allowed to limit coverage beyond the definition of covered outpatient drug.[50] Restrictions or exclusions are allowed for a particular list of reasons.[51] The state may also choose to create its own formulary[52] or require

[44] **Id.**

[45] States may choose to **expand this definition to also include nonprescription dregs. 42 U.S.C.A.** § 1396ró8(kX4) (West Supp. 1994).

[46] Federa1 Food Drug & Cosmetic Act of 1938 §§ 505,507, codified at 21 U.S.CA. §§ *355,* 357.

[47] Drug Amendments Act of 1962, Pub. L No. 87-781, § 107(c)(3).

[48] 42 U.S.C.A. § 1396r-8(kX3) (West Supp. 1994).

[49] **42 U.S.C.A.** § **1396r-8(kX6) (West Supp. 1994). Compendia allowed for this purpose include the American Hospital Fornudmy Service Drug Information, the U.S. Pharmacopoeia-Drug Information, and the Amican Medical Associate Drug Evaluations. 42 U.SC.A.** § 1396r-8(gXlXBXi) **(West Supp. 1994).**

[50] 42 U.S.C.A. § **1396r-8(d) (West Supp. 1994).**

[51] These include anorexia and weight loss drugs, fertility drugs, hair growth drugs, nonprescription drugs, ami vitamins. 42 U.S.C.A. I 1396r-8(dX2) **(West Supp. 1994).**

[52] 42 U.S.C.A. § 1396r-8(dX4) **(West Supp. 1994).**

prior approval for drug coverage.[53]

Unlike cases arising under Medicare, plaintiffs have generally had more success in requiring Medicaid to reimburse drugs despite initial coverage denials, if medically necessary.[54] This is true even for uses unapproved by FDA.[55]

C.Medicare Catastrophic Coverage Act of 1988

The Medicare Catastrophic Coverage Act of 1988 (MCCA) provided for a number of new Medicare benefits, including drug coverage, largely designed to expend coverage for the elderly.[56] Although the statute was short-lived and the benefit never implemented, we do have a relatively clear outline of the proposed benefit from the statute, legislative history and proposed regulations.

The basic statutory definition[57] of a covered outpatient drug is essentially taken from the Medicaid statute.[58] The statute further excludes certain services aiready covered elsewhere in the Medicare statute.[59] The statute states that the Secretary shall establish for each outpatient drug standards which are based on accepted medical practice.[60] These standards shall incorporate

[53]42 U.S.C.A. § 1396r-8(dXlXA) **(West Supp. 1994).**

[54]**~.g,, Weaver v. Reagen, 886 F.2d 194(8th Cir. 1989) (holding that Missouri must reimburse AZT when physicians had certified that treatment was medically necessary).**

[55]886F.2dat 198.

[56]John K. Iglehart, Medicare's New Benefits~ Catastrophic Health Imurnm~~ 320 NEW ENG. J. MED. 329, 329-30(1989).

[57]MCCA, Pub. L No. 100-360, §202(a)(2XC), 102 Stat. 702-03(1989).

[58]Comvar~ 42 U.S.C.A. § **1396r-8(kX2) (West Supp. 1994). This language is actually broader than either the House or Senate bills' language had been. H. Conf. Rept. No.100-661,100th Cong., 2d Sees. 185(1989) (Conference Report),** r~intulia **1989 U.S.C.C.A.N. 923,963.**

[59]MCCA, Pub. L No.100-360, §202(a)(2XC), 102 Stat. 703 (1989).

[60]MCCA, Pub. L No. 100-360, §2(12(b)(4), 102 Stat 708-09(1989).

authoritative compendia[61] modified by scientific and medical information that such standard is not consistent with the safe and effective use of the drug.[62] The statute explicitly prohibits the creation of a Medicare formulary.[63] The reasonable and necessary statutory requirements already contained in the Medicare statute would also still apply.[64]

The Health Care Financing Administration (HCFA) Notice of Proposed Rulemaking placed in the Federal Register following passage of the MCCA gives further indications of how the MCCA drug benefit would have been implemented. For example, the proposal makes clear that, unlike Medicaid, prescription drug really means only prescription drugs and may not include non-prescription drugs.[65] The proposed regulations confirm that drug standards promulgated under the act will use the three compendia mentioned in the Conference Report[66] and that any deviation from the compendia must use rulemaking procedures.[67] The proposed regulation asserts that payment may not be made for specific uses which HCFA finds are not safe and effective for the diagnosis or treatment of illness or injury.[68] However, the proposal also states that standards would not be used to define coverage or payment of covered

[61] P˜ Conference Rq˜ort expects that compendia will include the U.S. Pharmacopoeia Dispensing Information, the American Medical Association's Drug Evaluations, and the American Hospital Formulary Service Drug Information. Conference Report at 192, r˜axiatmIin **1989 U.S.C.C.A.N. 923,970.**

[62] MCC˜ Pub. L No. 100-360, §202(bX4), 102 Stat 709(1989).

[63] ˜

[64] **notes 37-40 and accompanying text. Also noted in Conference Report at 191,** r˜xin1ad.iu **1989** U.S.C.C.A.N. 923,969.

[65] ***54*** Fed. Reg. 37,196(1989).

[66] 54 Fed Reg. 37,208(1989) **(to have been codified at 42 C.F.R.** § 410.32) (proposed Sept. 7, 1989).

[67] Id.

[68] 54 Fed Reg. 37,207(1989) (to **have been codified** at 42 C.F.R. § 410.30(d)) (proposed Sept. 7, 1989).

outpatient drugs under the Act.[69]

D. The Clinton Health Security Act

On October 27,1993, President Clinton presented his Health Security Act of 1994 (HSA) to Congress. Even though the legislation was eventually not acted on by Congress, it was extensively analyzed in both academic settings and in the media and thus provides another possible model of prescription drug coverage under a government plan. However, because the legislation was not enacted nor fleshed out, the terms are substantially more vague than an enacted statute (MCCA) or existing programs (Medicare, Medicaid).

Inmanyways,theClifltonplafl15atlea5ttwoplan5inoneforthePIfl1˜OseSofdrug coverage. Drugs are included as a new benefit under Medicare and are also included as part of the Comprehensive Benefit Package which would be a floor for health packages guaranteed to the general public.

The new benefit under Medicare, like the new benefit proposed under the MCCA, adopts the Medicaid definition of a covered outpatient drug.[70] However, the HSA definition of medically accepted indication is slightly expanded from the Medicaid and MCCA deflnitionL Under the HSA, medically accepted indication includes uses (1) for which the drug has been approved for use by the FDA and (2) other uses if the drug has been approved by the FDA and either the use is supported by the usual compendia[71] or the carrier involved determines that such use is medically accepted based on peer review medical

[69] **54 Fed. Reg. 37,200(1989).**

[70] **3600/5. 1757, 103d Cong., 2d** Sess. (HSA) § 2001(2Xb)(3) (1994).

[71] hi this case the U.S. Pharmacopoeia - **Drug Information, the American Medical Association Drug Evaluatione, and the American Hospital Forinulary Service - Drug Information.** Id8

literature.[72] As in the MCCA, the legislation provides for promulgation of outpatient drug standards based on compendia and modification by regulation.[73]

The drug benefit in the Comprehensive Benefit Package refers to the (amended) Medicare definition of covered outpatient drug and medically accepted indication except that the Secretary (the Board in an earlier draft) is substituted for the carrier in determining whether a use is medically accepted based on clinical evidence in peer review medical literature?[74]

II.An Analysis of Differences Between the Four Drug Coverage Schemes

To a large extent the differences between the four drug coverage schemes are minimal. Three of the four (Medicaid, MCCA and HSA) essentially define a covered outpatient drug in the same manner. All utilize FDA approval as a way of certifying a drug's safety and effectiveness to some extent However, there are significant differences both between the MedicaidIMCCAIHSA definition and Medicare's drug definition and among all four in terms of how much flexibility the government has in defining drug coverage.

The Medicare definition of drug, at least textually, appears to be broader than the other definitions. While the MedicaidIMCCA/HSA definitions state that a drug (1) must be a prescription drug and (2) must either be FDA-approved or not otherwise FDA-disapproved (i.e. a pre-1962 old drug or a drug to which the 1962 Amendments did not apply), further coverage requirements allow reimbursement for medical accepted indications as defined either by FDA

[72]Id.
[73]H5A § 2002(a) (1994).
[74]H5A § 1 122(aX2).

approval or by inclusion in a compendia. The Medicare drug definition looks first to either compendia or approval by a medical staff FDA approval for the approved use counts as if in the compendia.

Examining these two definitions textually, there are a few possible points of departure. First, a drug may be recognized as a drug by an applicable compendia but which is not approved by FDA. This type of drug would more likely be reimbursable under Medicare than under the MedicaidIMCCA/HSA definition. Similarly, a drug which is disapproved by the FDA may still be eligible for reimbursement under Medicare Part A (though Part B makes a specific exclusion for this situation) if either the drug is included under a compendia listing or the medical staff thinks the drug should be included in treatment On the other hand, since Medicare reimbursement is limited to those treatments which are reasonable and necessary, this may even out some of the possible inequities. For example, experimental drugs are excluded under Medicare's reasonable and necessary standard, but may nevertheless be covered under the MedicaidIMCCAIHSA definition This is similarly true with drugs which are not cost-effective. Finally, and in some ways most importantly, because Medicare is limited to facility-based care and generally excludes self-administrable drugs, many more outpatient prescription drugs are and would be approved under the MedicaidIMCCAIHSA schemes.

Among the MedicaidIMCCAIHSA definitions, HSA's definition of medically accepted indication provides slightly more discretion than the other two because it permits carrier discretion to approved reimbursement for uses

not approved by the FDA. This does not exist either in the MCCA or Medicaid definition.

Each scheme provides significant flexibility to deviate from the basic drug coverage definition. Medicare allows flexibility on a number of levels. First, coverage may vary on the medical staff leveL This reflects our general tendency not to want to interfere with the practice of medicine by health professionalL Coverage may also vary on the carrier level. Since carriers have responsibility for deciding what is reasonable and necessary in the absence of Medicare direction, they may make significant drug coverage decisions. HCEA may also issue directives at a national level through a physician panel process, although they have rarely done this.

In con˜st, states under Medicaid may define whether or not to cover drugs at all under their health plans. They may also decide whether to use the baseline drug requirements or to be even stricter. Rir example, states may set up formularies listing drugs they will reimburse. However, formularies may give less flexibility than it first appears. Because state Medicaid programs are required to provide all medically necessary health care, state Medicaid programs may be forced to include drugs recognized as effective, regardless of cost?[75] For example, in 1992 three plaintiffs successfully sued the state of New York to have clozapine, an anti-schizophrenic drug approved by the FDA and for which there was no low cost alternative, included in the New York State Medicaid Formulary.[76] Because there is no check for cost-effectiveness, this is in some

[75] **42 U.S.C.A.x 1396r-8(dX4XC) (West Supp. 1994).**

[76] Alexander L v. Cuoxno, 588 **N.Y.S.2d 85 (Sup. Ct. 1992).** ˜ alan **Mair** v. Barton,

ways less flexible than Medicare. Medicaid plans can also require prior approval systems.

MCCA, while using the Medicaid definition of a drug, did not offer the same kind of flexibility as Medicaid. However, since it was designed as an addition to the Medicare program, drugs would still be subject to the reasonable and necessary statutory requirement Some flexibility issues are simply not clear. Although the statute calls for HCFA to investigate the safety and effectiveness of drugs independent of FDA's determination, establish standards for each outpatient drug, and to not make payment for uses that HCFA finds are not safe and effective, the statute also prohibits the creation of a formulary and regulations confirm that though rulemaking proceedings would be necessary to deviate from standards derived from accepted medical compendia, standards would not be used to define coverage or payment. Thus is unclear how much discretion HCFA would have had in setting coverage boundaries had the MCCA plan been implemented.

The HSA, as in the present Medicare system, would have given significant flexibility to carriers to determine coverage if HCFA, the FDA, and compendia do not address coverage. However, like the MCCA, the HSA provided for outpatient drug standards. Unlike the MCCA, there is no explicit prohibition against either having a formulary or against using the standards to define coverage. Interestingly, the health care benefit offered under the comprehensive benefit package does not delegate analogous authority to address

705 F. Supp. 520 (D. Kan. 1987) (forcing AZT **to be included in Kansas' Medicaid formulary).**

coverage vacuums to insurers (the logical analogy to carriers) but rather to the Secretary of HHS. This essentially means that, assuming that some plans opt for a minimal drug benefit, that the Medicare benefit may be more inclusive (based on carrier discretion) than the minimum comprehensive benefit package.

III.Some Important Coverage Issues Regarding Government Drug Reimbursement

In this section 1 examine a number of the most important coverage issues surrounding provision of a drug benefit under a government health insurance plan. The discussion is organized topically into three questions, but issues involved in responding to the questions necessarily overlap. For example, cost-containment is a concern for all three questions.

A. Should a drug benefit exist at all?

In many ways it is a reasonable question to ask whether a drug benefit should exist at all. Although there may be need, particularly among some elderly, won't a benefit simply wind up costing too much money to implement? Won't people overutilize covered drugs? Perhaps our money could be better spent elsewhere. Medicare Part B has survived without a drug benefit˜

These are not meritless arguments. Nevertheless, numerous studies have shown that the market for medical drugs is a favorable one for insurance.[77] Drug spending among the elderly is a skewed distribution. The 11 percent who spend the most on drugs account for nearly half *(45* percent) of total drug spending?[78] As long as these high costs are not foreseeable, it makes sense to have insurance to spread the risk2[79]Especially in terms of a national health plan

[77]Long, ˜j note 11 at 159.
[78]Id.
[79]**soma point risk does become obvious, and then** adverse selection (the idea that

that includes all elderly (thus discouraging adverse selection), it appears to make sense to have insurance. In contrast, the present system forces many to pay for drugs out-of-pocket; *55* percent of the $36 billion paid for prescription drugs in 1991 was paid without insurance.[80] There is also a serious disparity between those that do and do not have insurance. Most of the elderly that do have drug insurance have it through employer-sponsored plans.[81] Thus, as elders move out of the work force, they are likely to lose prescription drug coverage when they most need iL Although Medicaid often covers drup, this is only applicable to the poorest in society.

A prescription drug benefit would likely increase utilization of drugs.[82] However, this is not necessarily a bad thing. Studies have shown that increased utilization from a drug benefit has gone more to fulfill unmet need than toward overutilization.[83] This makes sense since, given the present system (for many elders) where medical procedures are covered by insurance but prescription drugs (which could avoid the need for costly procedures) are not, people are less likely to take drugs (since they'd have to pay) and instead opt for the costly procedures (for which they won't have to pay) later. In lbct, using this logic, some studies have shown that imposed limits on drug coverage in some cases resulted in an actual increase in health care costs and increased institutionalization of

only those who need the **insurance - the high risk high cost people - will purchase insurance, thus 6iling to spread risks at all) is a wony.**

[80]Id. This is in fact one of the argun˜nts for required or universal health insurance. If ˜u purchase insmrance before risks are clear, there is no adverse selection possibility.

[81]1d.at 161.

[82]M. Greenlick & **D. Benjamin, with UtilizAtion Under a Drug Prep˜,ment Plan 58 AM.** J. PUB. HEALTH 2121(1968), A. Liebowitz et aL, Iho**21 Soc Sc!.** & MED. 1063, lxplh˜itmt in **Sullivan,** note *5.*

[83]G˜iiJick & Bem˜jamin, uiiwn **note 82.**

the elderly.[84]

As a result of this evidence, it seems to make sense that insurance for drugs should at least be considered under any future health care reform, particularly for the elderly who are the largest users of prescription drugs. The present Medicare system of not having a drug benefit may actually be costing the health care system more in the long run. A secondary benefit to drug coverage is that it may encourage increased innovation by drug companies to develop new drugs. Because there will be increased utilization, drug companies will have more resources and incentives to find new drugs. However, this is by no means certain. In fact, the Pharmaceutical Manufacturers Association actually fought against the MCCA drug benefit because along with prescription coverage came strict price controls.[85] Thus the effect on the pharmaceutical industry is not clear.

B. How should coverage be related to FDA approval?

Even if drugs are covered under a health insurance plan, there is still a question of which drugs should be covered. One of the most important questions in this vein is what relation FDA approval should have to coverage. There are a number of different possibilities, ranging from covering only uses for which drugs were approved by FDA to deferring to physician discretion. Present coverage benefit proposals have generally been somewhere in the middle of these

[84]Stephen B. Soumeiui et al., Effects **of Medicaid Dnmg-Pavmamt Limits on Admission** to Hcuspitals ami **Nummg** lj˜, **323 NEW ENG. J. MED. 1072(1991).** ˜ alma **E.W. Lingle et al., Ihn.ILaL˜fhfg˜m3˜ on the Use and Costs of Health Care Services for the Elderly. INQUIRY, Fall 1987,** at **203,** ˜i1ml in **Sullivu˜,** uu˜a ***note 5.***

[85]lglehart, ˜ note 56, at 333; ˜ **CHAIN DRUG REv., Aug. 29,1994** at **Rx44.**

two extremes.

1.Deferral to FDA Determinations

Although arguments can be made for only reimbursing drugs approved by FDA for approved uses, this clearly places too much reliance on FDA. FDA's mission regarding drugs is to protect the public against drugs which are adulterated,[86] misbranded,[87] or otherwise not safe and effective[88] for use. The FFD&CA is not meant to substitute FDA's authority for the authority of medical professionals. This is exemplified by the fact a generally accepted as safe exemption to the new drug application requirement exists.[89] lf FDA had intended to regulate the practice of medicine, there would be no reason for a generally accepted exception; the only acceptance that should matter would be FDA's. Further, FDA has explicitly recognized that physicians may prescribe approved drugs for unapproved uses.[90] It would be costly and time-consuming for FDA to certify every possible drug use's medical necessity.

It is also unclear whether a health plan, and certainly a government health plan such as Medicaid, which requires coverage of medically necessary items˜ could legally refuse to cover a drug which had been recognized in the medical literature as effective.[91] Doctors are also much more likely to attempt

[86]FFD&CA I 501,21 US.C. ˜ **351.**
[87]FFD&CA § 502,21 **U.S.C.** § 352.
[88]FFD&CA § **201(p),** 21 U.S.C. I 32l(p) (definition of new drug).
[89]**Higgins, am nob 17. at** 24.
[90]l˜j, (citing 1974 case Kowaiski **v. Rees (no citation available).** ˜L Wickline v. State, 741 P.2d 613,228 Cal. Rptr. **661 (App. CL 1986) (hokling that doctor, not state, was not responsible when Medi-Cal approved fewer in-patientdays tban necessary); United States v. Evers, 453 F. Supp. 1141 (D. Ala. 1978) (holding that pbysician can prescribe drugs for unapproved uses). However, there are indications that some private insurers have started to use FDA approval for a specified use as the** *sine qua non* **for reimbursement**
[91]**Higgins, note 17, at 22.**

and discover inventive procedures and drugs to help their patient than the FDA is to quickly approve such measures. This is why the medical literature is so important.[92]

2.De1˜rral to Doctors

The opposite extreme is equally untenable. Though the Medicare statute states that there is a prohibition against federal interference with the practice of medicine,[93] health insurance reimbursement practices indisputably affect physicians.[94] In fact, this is precisely what is intended. To a certain extent, a major aim of government run health insurance is to not rely solely on physician discretion. In terms of cost control, it is essential that someone at some point beahictosaythatenoughisenough. Inthistimeoflimitedpublicresources,thereisnosensein reimbursing large amounts of public money for non-cost-effective treatments and drugs which could be better spent elsewhere. This is embodied in the Medicare reasonable and necessary standard.[95]

As managed care becomes more widespread, there is also the possibility not of deferring to doctors, but deferring to managed care organizations to make determinations as to what is best for its clients. Because managed care organizations receive fixed payments for their clients and because they want to retain their clients, they have incentives both to provide quality service and to reduce costs. The question of how drugs should be covered under managed care

[92] **˜ Higgins,** sum **note 17, at 24.**

[93] 42 U.S.C.A. §1395.

[94] **Richard E. Wild, Medicare Reimbursement for FDA Anproved Drugs: Medicare's Answer to United States v. Eves, 40 FOOD DRUG COSM. U. 382,382(1985).**

[95] **42 U.S.C.A. § 1395(yXaXl) (West Strpp. 1994).**

is certainly something to consider in future public health pIans.[96]

3.Somewhere In-Between

Our present systems, and most of the suggestions for future reform, are somewhere in between these two extremes. All four of the schemes examined above depart to some degree from reimbursing solely on the basis of FDA approval. Similarly, none look solely to the doctor's discretion. Most look primarily to FDA and to established compendia for most coverage decisions, with exceptions. Medicare, for example, makes a specific statutory exception for Group C cancer drugs. The schemes differ significantly in where they place the discretionary judgment in bordedine cases. Although Medicare's reasonable and necessary standard gives the program an effective way to limit coverage, discretionary decisions are made using the generally accepted medical practice in local areas, either by judgment of the medical staff or the Medicare carner. This may make patients nervous as they await decisions as to whether their ˜nent is or is not covered.[97] Further, as communications improve and as the discernible diffmnces existing between medical communities seem less reasonable, this practice may come un˜ question.[98] Medicaid formularies present one option, but they have been attacked when they don't keep up with current medical practice.[99] Both MCCA and HSA called for HCFA to s˜ drug standards for use (though MCCA precluded use of these standards for coverage reasons).

[96]**Mark V.** Pauly,, 24 SETONHALLL REV. **1271, 1285-88 (1994)**

[97]For an example, look at the reported hesitation of Medicare carries, a recent decisions to cover the anti-rejection drug FKSO6 f˜r off-labea uses. Bryon Space, ˜{˜˜IruaiImtfrag.Em1Ia.˜. *g˜mua* **PITF.** PUSr-43AZErrE, **Sept. 7,1994, at A10 Bryan Spice, , PITl˜. POST-GA7ErFE, Aug. 31,1994,** at B4.

[98]**Coleman,** jjin note 18 **at 102.**

[99]jj˜ **notes 75-76 ami accon˜ianying text.**

Perhaps this is a logical place to look for coverage guidelines˜ although at least one commentator is skeptical of HCFA's resources to comprehensively decide coverage issues.[100]

A further question is how experimental and investigational drugs should be covered. While Medicare generally does not cover these drugs under its reasonable and necessary standard, these drugs provide the only hope for many terminal patients. This partly explains the Group C cancer drug exception. While the HSA planned a committee to examine prices of breakthrough drugs, no mention was made of coverage issues for investigational and experimental drugL A system should be devised to allow individuals desperate for treatments to have some access (without the drug companies shifting the entire development cost onto the public insurer).

C. How should over-the-counter drugs be treated?

The ffip side to investigational and experimental drug coverage is coverage of over-the-counter (OTC) drugs. It is interesting to note that while costs for prescription drugs have increased quickly over the last ten years, costs have not similarly increased for nonprescription items.[101] Aside from the question of whether health care system costs could be saved by switching drugs WOTC status,[102] there are some who believe that increased coverage of prescription drugs by insurance will result in increased switches of prescription

[100] **CoIeman, note 18, at 102.**
[101] I..etech, hun **note 6, at** 98.
[102] Peter B. Hutt, Drugs **for Self4Aedication in tim Future,** 19 DRUG INFO. **J. 195,196-97(1985) (the political self-interests of pharmacists, physicians, and cfrug conq,anies may mitigate against** snoh a switch).

drugs to OTC status.[103] This may come either at the impetus of the manufacturers[104] or the public insurer, who desperately wants to reduce costs.[105] If many drugs do switch to OTC status, this could lead to pressure to extend insurance coverage to OTC drugs.[106] Some states presently choose to cover non-prescription drugs under their Medicaid plans.

Government reimbursement of drugs is likely to be an important part of any future health carereformeffort Itisinmanywaysanareawhichshouldbecoveredbyinsurancebutisnot Given that reimbursement may occur, it is important to examine how the limits of this coverage will be defined. Coverage must mesh with FDA drug approval, and must confront the physician's practice of medicine. Cost-effectiveness and cost control are also important. By looking at existing schemes for coverage of drugs under Medicare and Medicaid, as weil some of the other recent efforts to propose a drug benefit, we get some idea of the questions and possible answers which a drug benefit entails.

[103] Ricbard M. Cooper, **24 SETONHALLL REV. 1260,1260-61(1994).**
[104] **AS Cooper suggests,** id. **at 1261, though I agree with Hutt˜ IU˜I note 102, at 197 that this is ˜uiIlkely.**
[105] S˜v˜ example given in class (sorry, I tried to find documentation, bs* came ˜ short).
[106] Cooper, note 103, at 1263.